

**Notice of Allowability**

Application No.

10/018,001

Examiner

Matthew J Kremer

Applicant(s)

SAMUELS ET AL.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed on 1/24/2005.
2. ☒ The allowed claim(s) is/are 1,3-16,18-23,26-28,31-40 and 43-50.
3. ☒ The drawings filed on 11 December 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|   | 9. <input type="checkbox"/> Other _____.   |

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michael B. Lasky (Reg. No. 29,555) on 2/4/2005.

The application has been amended as follows:

In claim 1, line 3, "atissue" was changed to --a tissue--.

Claim 2 was rewritten as follows:

2. (Cancelled) ~~Claim 2 is cancelled.~~

In claim 4, line 3, "adiacent" was changed to --adjacent--.

Claim 6 was rewritten as follows:

6. (Currently amended) The ~~alignment device~~ system of claim 1, wherein the tissue interface member comprises of at least one clip that mates with a surface on the apparatus to hold the apparatus with respect to the tissue interface member.

Claim 7 was rewritten as follows:

7. (Currently amended) The ~~alignment device~~ system of claim 6, wherein the clip is biased to hold the first apparatus and second apparatus under tension.

Claim 10 was rewritten as follows:

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10. (Currently amended) The ~~alignment device~~ system of claim 8, wherein the exterior surfaces of the tissue interface member engage with surfaces of the apparatus to align the apparatus with the tissue interface member.

Claim 11 was rewritten as follows:

11. (Currently amended) The ~~alignment device~~ system of claim 8, wherein the tissue interface member comprises a male alignment member or a female alignment member that mates with a complementary female alignment member or a male alignment member, respectively, on the apparatus.

Claim 12 was rewritten as follows:

12. (Currently amended) The ~~alignment device~~ system of claim 1, wherein the tissue interface member comprises at least one magnetic surface portion to mate with at least one complementary magnetic surface portion on the apparatus.

Claim 13 was rewritten as follows:

13. (Currently amended) The ~~alignment device~~ system of claim 1, wherein the tissue interface member comprises a threaded member that mates with a complementary threaded member on the apparatus.

In claim 16, line 4, "with the tissue" was deleted.

Claim 17 was rewritten as follows:

17. (Cancelled) ~~Claim 17 is cancelled.~~

Claim 21 was rewritten as follows:

21. (Currently amended) In combination, the ~~alignment device~~ system of claim 1, and a tissue breaching device for mechanically breaching the tissue and forming at least one

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opening therein, wherein the tissue breaching device comprises at least one alignment member that mates with the tissue interface member to achieve alignment with the tissue.

Claim 22 was rewritten as follows:

22. (Currently amended) In combination, the ~~alignment device~~ system of claim 1, and a tissue breaching device comprising a heatable element for breaching the surface of the tissue by thermally ablating the tissue to form at least one opening therein, wherein the tissue breaching device comprises at least one alignment member that mates with the tissue interface member to achieve alignment with the tissue.

In claim 23, line 8, "in" was deleted.

In claim 23, line 8, "alignmnet" was changed to --alignment--.

In claim 27, line 1, "where in" was changed to --wherein--.

In claim 27, line 2, "thereofto attach" was changed to --thereof attachable--.

Claims 28-30 were rewritten as follows:

28. (Original) The system of claim 27, wherein the energy absorbing layer is simultaneously removed upon detachment of the tissue breaching apparatus. ~~Claims 29 and 30 are cancelled.~~

Claims 29-30. (Cancelled)

In claim 32, line 6, "oftne" was changed to --of the--.

In claim 40, line 3, "ofthe" was changed to --of the--.

Claims 41-42 were rewritten as follows:

Claims 41-42. (Cancelled) ~~Claims 41-42 are cancelled.~~

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In claim 44, line 10, "fmiher" was changed to --further--.

In claim 44, line 16, "apparahls" was changed to --apparatus--.

In claim 45, line 10, "ofthe" was changed to --of the--.

Claims 51-57 were rewritten as follows:

Claims 51-57. (Cancelled) ~~Claims 51-57 are cancelled.~~

2. The following are the reasons for the amendment. In regard to claims 1, 4, 16, 23, 27, 32, 40, 44, and 45, the amendments were made to correct minor typographical and grammatical errors and no modification of the scope of the claim is intended. In regard to claims 2, 17, 29-30, 41-42, and claims 51-57, the amendments were made to conform with the Office's policy of requiring appropriate status modifiers. In regard to claim 28, the amendment was made to correct a formatting error in the listing of claims in the amendment filed on 1/24/2005 and no modification of the scope of the claim is intended. In regard to claims 6-7, 10-13, and 21-22, the claims were amended as a result of the claims being rejoined in view of allowable claim 1. (see below)

3. Claim 1 is generic and allowable. Accordingly, the restriction requirement as to the encompassed species is hereby withdrawn and claims 6-7, 10-13, and 21-22, directed to species of B-C and I-II, and IV-VII are no longer withdrawn from consideration since all of the claims to this species depend from or otherwise include each of the limitations of an allowed generic claim. Claim 1 is considered generic since the specification clearly teaches that the several species of the embodiments were combinable with each other. (see page 8, lines 3-5 and page 14, lines 19-21 of the specification).

In view of the above noted withdrawal of the restriction requirement as to the linked species, applicant(s) are advised that if any claim(s) depending from or including all the limitations of the allowable generic linking claim(s) be presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or

nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. In view of the papers filed 10/21/2002, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of Mark Vreeke as a co-inventor.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 571-272-4727. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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ERIC WINAKUR  
PRIMARY EXAMINER  
